REMARKS

I. STATUS OF THE CLAIMS:

Claims 25, 27 and 29-37 are pending. Claims 25, 32 and 35-37 have been amended to recite that the release of tranexamic acid occurs over a period of about 120 minutes. Support for these amendments can be found in the specification on page 7, lines 17-19. Applicants respectfully submit that no new matter has been added by virtue of these amendments.

II. REJECTION UNDER 35 U.S.C. § 102

In the Office Action, the Examiner rejected claims 25, 27, 29, 32 and 35-37 under 35 U.S.C. § 102(b) on the grounds of being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,575987 (hereinafter "the Kamei patent"). The Examiner stated, *inter alia*, that:

> "Kamei discloses sustained release microparticles containing biologically active substance and biodegradable polymer...; the bioactive substance includes hemostatic agent, of which tranexamic acid is named...; the oral preparations also contain cellulose materials that ensure extended release of the drugs in the intestines.... Also, because the release of the active is retarded in the intestines in Kamei, it flows that the active substance is also inherently retarded in the stomach... In the alternate, the fact that the drug formulation of the prior art comprises the same excipients named in applicant's specification as contributing to controlled/sustained release of tranexamic acid, it flows that the presence of these excipients in the formulation of Kamei leads to the inherent ability of the formulation of the prior art to be delivered/released at any where [sic] in the GI tract, or retarded anywhere in the GI tract."

This rejection is respectfully traversed. Independent claims 25, 32, and 35-37 of the present invention have been amended to recite that the release of tranexamic acid occurs over a period of about 120 minutes.

In contrast, the Kamei patent describes dosage formulations containing water-in-oil microcapsules "adapted to release a biologically active substance at a calculated rate over a protracted time period starting immediately following administration without an initial burst within one day following administration" (See: Kamei patent Abstract and at column 1, lines 9-14). Nowhere does the Kamei patent teach or suggest that the active agent is released over a period of about 120 minutes as claimed in the present invention. In fact, the formulation exemplified in the Kamei patent exhibited a one-day drug release that ranged from 4.9% to 13.2% (Kamei patent Tables 1-5), which is not even close to a release over a period of about 120 minutes. Accordingly, independent claims 25, 32 and 35-37 and the claims that depend there from are not anticipated by or obvious over the Kamei patent. Therefore, Applicants respectfully request that the Examiner's 102 and 103 rejections be removed.

The Examiner also rejected claims 25, 27 and 29-37 under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,575,987 (Kamei et al.) in view of Cooper et al. ("A randomized comparison of medical and hysteroscopic management in women consulting a gynecologist for treatment of heavy menstrual loss"). The Examiner relied on the Cooper reference for teaching that "bloating is one of the symptoms of one who is suffering from menorrhagia and that tranexamic acid is know to be administered to persons having menorrhagia...." and concluded that "...it would have been obvious to one of ordinary skill in the art at the time the invention was made to administer tranexamic acid to a person in need thereof with the expectation that the tranexamic acid would relieve some of the symptoms of the menorrhagic condition."

This rejection is respectfully traversed. As discussed above with respect to the Kamei patent, Kamei does not teach or suggest that the active agent is released over a period of about 120 minutes as claimed in the present invention. The Cooper reference does not cure the deficiencies of the Kamei patent as Cooper describes that in one arm of the study, subjects received medical treatment with 1 gram of tranexamic acid administered four times a day. Nowhere does the Cooper reference teach or suggest a tranexamic acid formulation wherein: i) tranexamic acid release is retarded in the

stomach, but substantially released in the small intestine (claim 25); ii) tranexamic acid release is provided in both the stomach and intestines, such that a bolus of tranexamic acid does not reach the lining of the stomach and intestines resulting in decreased stomach concentration of tranexamic acid after ingestion (claim 32); iii) tranexamic acid release is provided in both the stomach and intestines thereby decreasing at least one gastrointestinal adverse effect (claim 35); iv) the formulation is an extended release, and/or delayed release formulation (claim 36); or iv) release of tranexamic acid is delayed until the small intestine (claim 37). Furthermore, the Cooper reference does not teach or suggest a formulation wherein tranexamic acid release occurs over a period of 120 minutes as claimed in the present invention. Accordingly, claims 25, 27 and 29-37 are not obvious over the Kamei patent in further view of the Cooper reference. Therefore, Applicants respectfully request that the Examiner's rejection be removed.

The Examiner also rejected claims 25, 27 and 29-37 under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,575,987 (Kamei et al.) in view of U.S. Patent No. 6,197,331 (Lerner et al.) in further view of Cooper et al. ("A randomized comparison of medical and hysteroscopic management in women consulting a gynecologist for treatment of heavy menstrual loss"). The Examiner relied on the Lerner patent for teaching treatment of "vomiting, nausea, gerd and reflux disease with compositions containing tranexamic acid and excipients."

This rejection is respectfully traversed. Kamei and Cooper are as discussed above. The Lerner patent cannot cure the deficiencies of the Kamei patent or the Cooper reference. The Lerner patent describes controlled release solid compositions or oral patch compositions that adhere to the hard dental surfaces, such as the teeth and dentures, and release the pharmaceutical agent in the oral cavity (See: Lerner: col. 1, lines 9-12; col. 6, lines 38-45; col. 6, line 56 to col. 7, line 19; col. 9, lines 12-58). Nowhere does the Lerner patent teach or suggest that the compositions described therein substantially release or delay release of tranexamic acid in the small intestine, nor does it teach or suggest compositions that release the tranexamic acid in both the stomach and intestines, let alone a formulation wherein tranexamic acid release occurs over a period of 120

minutes as claimed in the present invention. Accordingly, 25, 27 and 29-37 are not obvious over the Kamei patent in view of the Lerner patent and in further view of the Cooper reference. Therefore, Applicants respectfully request that the Examiner's rejection be removed.

V. CONCLUSION

This Amendment is being submitted together with a petition for a one-month extension of time and the $60.00 fee due under 37 C.F.R. § 1.17(a)(1). The Commissioner for Patents is hereby authorized to charge said fee to Deposit Account No. 50-0552. It is believed that no additional fees are due for this Amendment and petition. If it is determined that any additional fees are due, the Commissioner is specifically authorized to charge said additional fees to Deposit Account No. 50-0552.

Respectfully submitted,

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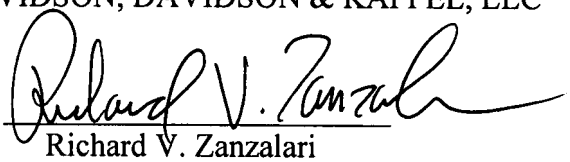
By: 

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